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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/076,571 | 02/19/2002 | Michael R. Johnson | 213706US96 | 1283 |

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MCKENZIE, THOMAS C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,571

Applicant(s)

JOHNSON, MICHAEL R.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-124 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-124 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. This action is in response to an application filed on 2/19/02. There are one hundred twenty-four claims pending. Claims 1-84 and 119-124 are compound claims. Claims 85, 117, and 118 are composition claim. Claims 87-116 are use claims. The application concerns some acyl guanidine linked phenoxy compounds, compositions, and uses thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims parts of 1-11, 57, 61-86, 119, and 120, drawn to asymmetrical triazine compounds wherein the ring containing Q is an asymmetrical triazine, classified in class 544, subclass 182.
- II. Claims parts of 1-11, 57, 61-86, 119, and 120, drawn to 1,3,5-triazine compounds, wherein the ring containing Q is a 1,3,5-triazine, classified in class 544, subclass 219.
- III. Claims parts of 1-11, 57-59, 61-86, 119-121, and 123, drawn to pyrazine compounds, wherein the ring containing Q is a pyrazine, classified in class 544, subclass 238.

- IV. Claims parts of 1-11, 57-59, 61-86, 119-121, and 123, drawn to pyrimidine compounds, wherein the ring containing Q is a pyrimidine, classified in class 544, subclass 295.
- V. Claims parts of 1-11, 57-59, 61-86, 119-121, and 123, drawn to pyridazine compounds, wherein the ring containing Q is a pyridazine, classified in class 544, subclass 357.
- VI. Claims parts of 1-12, 57-60, 61-86, and 119-124, drawn to pyridine compounds, wherein the ring containing Q is a pyridine, classified in class 544, subclass 405.
- VII. Claims 13-56 and parts of 1-12, 57-60, 61-86, and 119-124, drawn to phenyl compounds, wherein the ring containing Q is a phenyl, classified in class 544, subclass 407.
- VIII. Claim 87 and part of 89, drawn to a method of hydration, classified in class 514, subclass 242, among others.
- IX. Claim 88 and part of 89, drawn to a method of restoring defense, classified in class 514, subclass 242, among others.
- X. Claim 90 and part of 89, drawn to a method of treating bronchitis, classified in class 514, subclass 242, among others.

- XI. Claim 91 and part of 89, drawn to a method of treating CF, classified in class 514, subclass 242, among others.
- XII. Claim 92 and part of 89, drawn to a method of treating sinusitis, classified in class 514, subclass 242, among others.
- XIII. Claim 93 and part of 89, drawn to a method of treating vaginal dryness, classified in class 514, subclass 242, among others.
- XIV. Claim 94 and part of 89, drawn to a method of treating dry eye, classified in class 514, subclass 242, among others.
- XV. Claims 95, 96, and part of 89, drawn to a method of promoting hydration XVI, classified in class 514, subclass 242, among others.
- XVI. Claims 97, and part of 89, drawn to a method of promoting clearance, classified in class 514, subclass 242, among others.
- XVII. Claim 98 and part of 89, drawn to a method of treating Sjogren's, classified in class 514, subclass 242, among others.
- XVIII. Claim 99 and part of 89, drawn to a method of treating intestinal obstruction, classified in class 514, subclass 242, among others.
- XIX. Claim 100 and part of 89, drawn to a method of treating dry skin, classified in class 514, subclass 242, among others.

- XX. Claim 101 and part of 89, drawn to a method of treating esophagitis, classified in class 514, subclass 242, among others.
- XXI. Claim 102 and part of 89, drawn to a method of treating dry mouth, classified in class 514, subclass 242, among others.
- XXII. Claim 103, 104, and part of 89, drawn to treating dry noses, classified in class 514, subclass 242, among others.
- XXIII. Claim 105 and part of 89, drawn to treating pneumonia, classified in class 514, subclass 242, among others.
- XXIV. Claim 106 and part of 89, drawn to treating asthma, classified in class 514, subclass 242, among others.
- XXV. Claim 107 and part of 89, drawn to treating dyskinesia, classified in class 514, subclass 242, among others.
- XXVI. Claim 108 and part of 89, drawn to treating otitis media, classified in class 514, subclass 242, among others.
- XXVII. Claim 109 and part of 89, drawn to inducing sputum, classified in class 514, subclass 242, among others.
- XXVIII. Claim 110 and part of 89, drawn to treating pulmonary disease, classified in class 514, subclass 242, among others.

XXIX. Claim 111 and part of 89, drawn to treating emphysema, classified in class 514, subclass 242, among others.

XXX. Claim 112 and part of 89, drawn to a second method of treating pneumonia, classified in class 514, subclass 242, among others.

XXXI. Claim 113, 114, and part of 89, drawn to treating constipation, classified in class 514, subclass 242, among others.

XXXII. Claim 115 and part of 89, drawn to treating diverticulitis, classified in class 514, subclass 242, among others.

XXXIII. Claim 116 and part of 89, drawn to treating rhinosinusitis, classified in class 514, subclass 242, among others.

XXXIV. Claim part of 89, drawn to all other methods of blocking sodium channels, classified in class 514, subclass 242, among others.

XXXV. Claim 117, drawn to a complex composition containing a P2Y2 inhibitor, classified in class 514, subclass 1, among others.

XXXVI. Claim 118, drawn to a complex composition containing a bronchodilator, classified in class 514, subclass 1, among others.

Claims 12, 60, 122, and 124 link Groups VI and VII.

Claims 58, 59, 121, and 123 link Groups III-VII,

Claims 1-11, 57, 61-86, 119, and 120 link Groups I-VII.

Claim 89 links Groups VIII-XXXIV

3. The inventions are distinct, each from the other because of the following reasons: the heterocyclic core of the structure given in claim 1 is the ring bearing variable Q. This ring is a mandatory feature and ranges in number of nitrogen atoms from zero to three. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I-VII have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II-VII. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Should Applicant traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicant should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence will be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

4. Inventions I-VII and VIII-XXXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case there are many other products capable of performing Applicant's claimed uses. For example vaginal dryness may be treated with K-Y jelly and asthma may be treated with steroids. Applicant admits that their products of claim 1 have at least twenty-seven distinct uses. Thus, both prongs of the test are met.

5. If Applicant selects one of the compounds groups, Groups I-VII, then he is invited to select a single use claim from Group VIII-XXXIV for examination. Applicant is reminded that MPEP § 806.05(h) refers to product and a method of use in the singular, not Applicant's twenty-seven different uses.

6. Inventions XXXV or XXXVI and I-VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because bronchodilators are well known anti-asthmatics. The subcombinations I-VII have separate claimed utility such as treatment of a vaginal

dryness distinct from asthma treatment. Simple compositions and those with an additional active ingredient are patentably distinct because the combination (complex composition) can be patentable even if the subcombinations (the individual compounds) are not. This is because of the possibility of synergistic interaction, which is usually the purpose of the complex composition in the first place. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group I-VI is not required for Group VII, restriction for examination purposes as indicated is proper.

7. If Applicant elects either of Groups XXXV or XXXVI, the complex compositions, then he must also elect a species of P2Y2 inhibitor or bronchodilator for purposes of classification and examination.

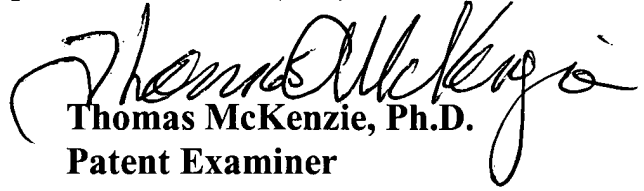
8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Conclusion

9. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30,

Art Unit: 1624

Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Thomas McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK
July 4, 2003

